Fenwal
A Fresenius Kabi Company

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510(K) SUMMARY

Date Prepared:

April 18, 2014

Owner and Contact Person:

Owner/Operator	Owner/Operator #: 9098803 Fenwal, Inc. Three Corporate Drive Lake Zurich, IL 60047
Contact Name: Title: Address: Telephone: Fax: E-mail:	Kim Forch Manager, Regulatory Affairs Fenwal, A Fresenius Kabi Company Three Corporate Drive, 2nd Floor Lake Zurich, IL 60047 847-550-7962 847-550-2960 kim.forch@fresenius-kabi.com

Device Trade Name:
AMICUS Separator System

Common Name/Usual Name:
Automated Separator, Blood Cell and Plasma, Therapeutic
Automated Blood Cell Separator (Centrifugal Separation Principle)

Classification Name:
Automated separators, used for separation of blood cells and plasma for therapeutic purposes, have not been classified under a regulation by the Center for Devices and Radiological Health due to pre-amendment status.

21 CFR 864.9245 Automated Blood Cell Separator
Automated blood cell separators which are based on centrifugation type technology have been classified by the Center for Biologics Evaluation and Research as Class II devices with Special Controls (Docket 2005N-0017, Final Rule, 30-Nov-07).

Product Code and Classification Panel:
LKN (Gastroenterology/Urology panel) - Unclassified (due to pre-amendment status)
GKT (Hematology panel) - Separator, Automated, Apheresis

Legally Marketed Device Under Which Substantial Equivalence is Being Claimed:
Fenwal is claiming substantial equivalence with the currently cleared version of the AMICUS Separator System. The AMICUS Separator System was most recently cleared for Therapeutic Plasma Exchange (TPE) under 510(k) K111702 on March 22, 2012. The AMICUS Separator System was most recently cleared for apheresis under 510(k) BK120082 on January 8, 2013. This includes all operating protocols and changes previously cleared for the AMICUS Separator System.

Device Description:
The AMICUS Separator System is comprised of the AMICUS separator instrument and a disposable apheresis kit specific to the procedure being performed. The instrument is a continuous-flow, centrifugal device that draws whole blood from a donor/patient, separates the blood into its components, collects one or more of the blood components, and returns the remainder of the blood components to the donor/patient. The instrument operates using pumps, clamps and valves that move donor/patient blood through a single-use, sterile fluid path disposable kit. The cells are centrifugally separated within the kit by density differences.

The operator is responsible for preparing and monitoring the donor/patient and operating and monitoring the AMICUS separator during the automatic blood collection cycle. The operator controls the separator through a touch screen. When necessary, the operator is warned of problems with messages on the screen and corresponding audible alarms.

Once the cell separation is complete, the operator removes the needle(s) from the donor/patient, dismantles the kit, and disposes of the kit in a safe manner. The kit is packaged in a recyclable plastic tray.

Modification to the Existing Device:
Software version 4.5 has been developed for use with the AMICUS separator. This new software provides several enhancements including functionality to perform an automated custom prime in Mononuclear (MNC) and Therapeutic Plasma Exchange (TPE) procedures to maintain isovolemia in patients with low blood volume and/or low hematocrit. Specifically, this option allows the operator to fill the kit tubing with a prescribed priming fluid (e.g., blood) after the set is primed with saline and before the patient is connected.

The software also provides functionality to pump saline to a patient when administering saline during a TPE procedure instead of administering it through gravity. It also includes additional input parameters and output values on the MNC and TPE procedure screens. For MNC, this includes *Product Volume and ACD in Product* output values designed to provide product information in line with FACT (Foundation for the Accreditation of Cellular Therapy) requirements. Also included are additional instruction screens to aid the operator in the steps of kit installation, as well as other minor enhancements and updates.

A new version of the AMICUS Separator Operator's Manual and associated Data Management Supplement has been created to include information relevant to software version 4.5. The operator's manual has been updated to reflect the new functionalities, input parameters and

output values added as a result of software 4.5 while retaining the current information relevant to software 4.4. The manual and supplement also include updates due to some minor enhancements. Additionally, the manual has been updated to include some instructions and appendices not related to the new software.

Statement of Intended Use:
The AMICUS Separator System is an automated blood cell separator intended for use in therapeutic apheresis applications and may be used to perform Therapeutic Plasma Exchange (TPE).

The AMICUS Separator System is an automated blood cell separator intended for use in the collection of blood components and mononuclear cells.

Indications for Use:
The AMICUS Separator System is an automated blood cell separator indicated to perform Therapeutic Plasma Exchange (TPE).

The AMICUS Separator System is an automated blood cell separator indicated for the collection of blood components and mononuclear cells.

The device is designed to collect products while maintaining an extracorporeal volume at or below 10.5 mL/kg and a donor post platelet count greater than or equal to 100,000 platelets/microliter.

Depending on the AMICUS Separator System apheresis kit used in the collection of products, the AMICUS Separator System has been cleared to collect:

- Platelets Pheresis, Leukocytes Reduced (single, double, or triple units)
- Platelets Pheresis, Leukocytes Reduced, Platelet Additive Solution (InterSol) (single, double or triple units)
- Red Blood Cells, Leukocytes Reduced (by apheresis)
- Mononuclear Cells
- Plasma
    - Fresh Frozen Plasma
        - Must be prepared and placed in a freezer at -18° C or colder within 8 hours after phlebotomy.
    - Plasma Frozen Within 24 Hours After Phlebotomy (PF24)
        - Must be stored at 1-6°C within 8 hours after phlebotomy and placed in a freezer at -18° C or colder within 24 hours after phlebotomy.
        - Indicated for replacement of non-labile clotting factors. This product is not equivalent to Fresh Frozen Plasma.
    - Plasma Frozen Within 24 Hours After Phlebotomy (PF24) Held at Room Temperature Up to 24 Hours After Phlebotomy (PF24RT24)

- Can be stored at room temperature for up to 24 hours after phlebotomy. Product must be placed in a freezer at -18° C or colder within 24 hours after phlebotomy.
- Indicated for replacement of non-labile clotting factors. This product is not equivalent to Fresh Frozen Plasma.

o Source Plasma

Platelet Pheresis (single, double, or triple units) may be manufactured from products that do not meet leukocyte reduction product standards. This does not apply to Platelet Pheresis, Platelet Additive Solution (InterSol) (single, double, or triple units).

Technological Characteristics as Compared to the Predicate Device
The technological characteristics of the AMICUS separator remain the same as the predicate AMICUS device. This includes the centrifuge system, fluid control system, safety management system (including safety sensors and alarms), and anticoagulant management system. The physical design of the AMICUS separator instrument is identical to the marketed AMICUS device. The AMICUS apheresis kits remain the same as the currently cleared kits, including design, materials and manufacturing methods. The data management capabilities remain the same as the cleared AMICUS device.

Performance Data:
Software verification, systems verification and systems validation were performed in support of this submission. The results of the testing were acceptable.

Conclusion:
Based on the validation and verification activities performed, the AMICUS Separator System modified with software 4.5 provides a device system that is substantially equivalent to the currently marketed AMICUS Separator System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 10, 2014

Fenwal, Inc.
Kim Forch
Manager, Regulatory Affairs
Three Corporate Drive
Lake Zurich, IL 60047

Re: K141019
Trade/Device Name: AMICUS Separator System
Regulation Number: None
Regulation Name: None
Regulatory Class: Unclassified
Product Code: LKN, GKT
Dated: April 18, 2014
Received: April 21, 2014

Dear Kim Forch,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

4. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K141019

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AMICUS Separator System

Indication(s) for Use:
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- Platelets Pheresis, Leukocytes Reduced, Platelet Additive Solution (InterSol) (single, double or triple units)
- Red Blood Cells, Leukocytes Reduced (by apheresis)
- Mononuclear Cells

Prescription Use: X	AND/OR	Over-The Counter Use:
21 CFR 801 Subpart D		21 CFR Subpart C

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

- Plasma
  - Fresh Frozen Plasma
    - Must be prepared and placed in a freezer at -18° C or colder within 8 hours after phlebotomy.
  - Plasma Frozen Within 24 Hours After Phlebotomy (PF24)
    - Must be stored at 1-6°C within 8 hours after phlebotomy and placed in a freezer at -18° C or colder within 24 hours after phlebotomy.
    - Indicated for replacement of non-labile clotting factors. This product is not equivalent to Fresh Frozen Plasma.
  - Plasma Frozen Within 24 Hours After Phlebotomy (PF24) Held at Room Temperature Up to 24 Hours After Phlebotomy (PF24RT24)
    - Can be stored at room temperature for up to 24 hours after phlebotomy. Product must be placed in a freezer at -18° C or colder within 24 hours after phlebotomy.
    - Indicated for replacement of non-labile clotting factors. This product is not equivalent to Fresh Frozen Plasma.
  - Source Plasma

Platelet Pheresis (single, double, or triple units) may be manufactured from products that do not meet leukocyte reduction product standards. This does not apply to Platelet Pheresis, Platelet Additive Solution (InterSol) (single, double, or triple units).

Prescription Use: X 21 CFR 801 Subpart D	AND/OR	Over-The Counter Use: 21 CFR Subpart C

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Benjamin R. Fisher -S
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